Technical Pneumonia Device Landscape Review

REPORT

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1. Background

Since the 1990s a one minute timer has been provided by UNICEF to Community Health Workers to assist manual counting of breaths. Recent research has identified a need to improve this tool and also look for other options to support community health workers in the diagnosis of pneumonia in children under five in resource poor settings. In early 2013 a workshop in Copenhagen identified 10 characteristics which taken together indicate a preference for an automatic device not dependent on manual response. There have been many suggestions for new automatic devices of varying complexity. Most of them can be eliminated on the basis of one or more of the Copenhagen characteristics and the technical criteria. Following on from the initial landscape analysis done as part of the Malaria Consortium project "Improved tools for the measurement of respiratory rate and oxygen saturation for the diagnosis of pneumonia".

2. Methodology

This report is to facilitate the selection of diagnostic devices for field testing in 4 countries results from a contract between the Malaria Consortium and Ashdown Consultants dated 16th April 2014. The contract asked for the technical evaluation of 21 respiratory rate counters and over 20 pulse oximeters, listed in an earlier short listing exercise prepared for the Malaria Consortium in February 2014. This list was, in part, derived from a longer list of 158 items provided by PATH.

The conclusions from a discussion held at the Malaria Consortium office on 13th May 2014 were also incorporated into this report.

2.1 Technical Criteria

Technical criteria defined in the list from February 2014 provide the basis for this evaluation.

The technical criteria can be summarised under the headings provided.

- Cost - total cost to cover product lifetime and guarantees on components
- Robustness - duration of replacement of batteries and any recharge cycle
- Scale - manufacturer's supply capacity, scalability and sustainability
- Applicability - including use for the age range 0 to 5 years
- Accuracy - sensitivity and specificity with details of the display
- Extensibility - use of the device for more than one function
- Availability - whether or not the device is available for testing

3. Results

3.1 Respiratory Rate Counters

The data presented in Table 2 of the initial landscape report from February 2014 has been reviewed and a number of the manufacturer's websites have been visited. The comments given in the February report have also been studied. A single page summary is presented in Table 1 which focuses on 3 technical criteria: Cost, Accuracy and Availability. This table includes a new item 22 which was discussed for the first time on 13 May. This consists of an upgraded timer which is expected to be available from UNICEF at low cost; this can be used on its own or together with coloured beads for counting breaths. In using both the ARI timer and the coloured beads together this avoids the problem of mental counting which is difficult for many CHWs.

Table 1. Respiratory Rate Counters

Type	Description	Cost	Accuracy	Availability	Possible device for inclusion in future research stages
Automated count	Philips Breath counter	Currently not available	No info	Available for research	Yes
	Malaria consortium	Not available	No info	Available for research	Yes
	Clinical Software	Needs iPhone	No info		No
	Woodsweb	Needs iPhone	No info		No
	Neal Kraus	Needs iPhone	No info		No
	BC children's Hospital/Lionsgate	Smart Phone + app	No info	Commercially available	Yes
Automated + sensor	Philips CO2	Not available	Depends on sensor	Commercially available	No
	Preventice	Needs computer	No info	Commercially available	No
	Philips	Not available	No info	Commercially available	No
	Philips equivital	Needs computer	No info	Commercially available	No
	Vivinoetics	Needs computer	No info	Commercially available	No
	Guardit/ IRISS	Not Available	**?**	Available soon for research	Yes
	Philips camera	Needs iPhone	No info	Commercially available	No
	Serdar yagci	Needs iPhone	No info	Commercially available	No
	Respisense		Does not show respiratory rate	Commercially available	No
	Zephyr	Needs computer		Commercially available	No
Indirect	Softrove sounds	Needs iPhone	No info	Commercially available	No
	sirius	smartphone	Not intended	Commercially	No

			for diagnosis	available	
	Insanys ECG	200USD		Commercially available	No
	Peng Li	Needs iPhone	No info	Commercially available	No
	Sotera	Needs computer		Commercially available	No
Automated count	Upgraded UNICEF timer	Low	Data needed	Not known	Yes
	Counting beads	Low	No info	Yes	Yes

Definitions

The categories "Automated Count" and "Automated + sensor" are intended to distinguish between different types of devices as follows. "Automated count" relies on the user to visually observe breaths, the sensor is the human eye, there are various devices proposed which provide timing and counting functions. This category is considered to be likely to provide the cheapest and most reliable device. "Automated + sensor" covers devices with a specific breathing sensor with a dedicated readout device. There are very few proposals in this category and the major problem is likely to be the cost of the sensor and its lifetime (disposable or reusable).

In general terms there is completely inadequate information available on cost to an extent which makes any decision difficult about the suitability of these devices for field testing. There is also very little information about the accuracy of devices, even those which are stated to be commercially available. It is implied that the project to field test the devices should have some targets for the accuracy of the resulting data. It was agreed that the UNICEF timer with beads was likely to provide the reference level of performance for all respiratory rate counters. This reference level has not yet been defined and will be part of the decision-making process of the technical consultation Malaria Consortium is convening in Geneva on the 16/17th June 2014.

The data on availability is equivocal since a statement of commercial availability without a clear cost statement is meaningless. All devices which rely on an iPhone or a computer are too expensive and are considered to be impractical in the hands of Community Health Workers from maintenance and ethical perspectives. They have therefore not been considered in detail. It may be possible to consider devices based on smartphones since these are significantly cheaper than iPhones. However there is no clear costing available for any of the devices which are based on smartphones.

3.2 Pulse Oximeter devices

The list of 24 pulse oximeters which was provided has been divided into 4 categories for the purposes of this report 1) mobile phone applications, 2) finger pulse oximeters, 3) handheld pulse oximeters, 4) other.

Mobile phone applications

There are 5 devices in this category which are listed in terms of the cost of the application varying from free to USD 150. These all require a mobile phone, typically an iPhone 4S which is quoted from

Apple at £349. These are not apps for a simple mobile telephone as used in developing countries. For cost and complexity reasons this group was eliminated from the selection process. There are easier and cheaper means available to carry out pulse oximetry measurements. Subsequently, Lionsgate have presented a combined respiratory rate timer and pulse oxymeter app which can be used on an android phone. This looks interesting and warrants further analysis.

Finger pulse oximeters

There are 8 pulse oximeters in the list provided which is a selection from well over a hundred to be found on the internet at prices ranging from $20 to $250. These popular devices come from many manufacturers with a built-in display and are battery powered. They clip onto a finger.

The size of these devices makes them implausible/difficult for use on small children and some which are named as paediatric devices have a statement of a minimum age of 2 or 3 years or a minimum weight for the patient. Most make no clear statement of the intended age range. There are no statements available about the expected lifetime of the devices which have built in LEDs and a sensor to generate the signal. These components typically have a lifetime of less than 1 year and there are no guarantees to be found on the internet on the lifetime of finger pulse oximeters. Battery lifetimes for AAA batteries are quoted at 10 to 30 hours. The logistic problems and cost of supplying small batteries on this scale in developing countries rule out the use of devices which need replacement batteries at this rate of consumption. A rechargeable battery such as that found in a mobile telephone is essential for widespread easy use.

Two of the eight models have rechargeable batteries but one of these has a minimum age range of 3 years. The findings are summarised in table 1 which highlights in red the reason for not enquiring further.

An additional device was subsequently procured from Contec, which is potentially suitable for use with small children and has rechargeable batteries.

Table 1.Finger pulse oximeters

No in list	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
Company	Shanghai berry	Narang medical	Narang Medical	Global Care Market	SPO	Amperor	BV Medical	Clinical Guard	Contec
Model		DP2043	DP2047			MD300CS	*Not found*	300PN	CMS50QB
Oximeter Cost USD	30.00	33.60	50.40	53	*250*	50	100	93	67
Extra	*Smartph*								

items **Costs USD**	*one*								
Sensor life **(months)**									
Warranty **(years)**		NO INFO	NO INFO			NO INFO			
Rechargeable **Battery type/costs**		NO INFO	NO INFO	Li		yes		Not used	yes
Recharge **Life (hours)**				10					
Recharge **Time** **(hours)**									
Batteries						2AAA	2AA	2AAA	1 3.6V
Battery **life**								30	300
weight						25g			35g
Bargraph		yes	yes	yes		yes		yes	yes
waveform	yes	yes	yes			yes		yes	
Age range				3-12 years					Potentially 0-5 years
Possible	no	no	no	no	no	no	no	no	yes

Handheld pulse oximeters

There are 7 pulse oximeters in this category which consists of a handheld electronic device with display and a small sensor connected by a wire to the patient which usually is attached to the patient's finger. The handheld devices are cheaper and more convenient than the table top devices costing $1000 to $3000 which were formerly used. In this survey we looked at a price range of $ 115 to $450 for the device. The major cost of using all pulse oximeters has however been the cost of replacement sensors. The normal practice among the major manufacturers has been to charge about $100 for a sensor with a manufacturer specific connector. Sensors typically have a lifetime of not more than 3 months and no guarantee on their lifetime. These high costs have effectively prevented the use of pulse oximeters in developing countries for the past 40 years since these devices were invented.

A charitable organisation called Lifebox was recently set up by a global group of Anaesthetists with the aim of delivering affordable pulse oximetery to 70,000 anaesthesiology departments worldwide using a sensor with a guaranteed life of 1 year at the low cost of $25. This organisation sells the electronic device for $250 and has so far delivered 7000 units to more than 50 countries. This device with a low-cost, long-life sensor therefore sets the standard for comparison relevant to the other 6 devices listed. The primary criteria for comparison are cost, system lifetime and manufacturer capability.

The results are summarised in Table 2. Daray (14) and SDI (19) can be eliminated on grounds of high cost. Hopkins (21) has sensors which are clearly of short life and therefore less useful. Enquiries were sent to UTECH, Aeon and Narang asking for details not given on their websites. Narang have not replied but there are similar quotations from UTECH and Aeon which can validly be compared with the Lifebox.

Table 2.Handheld pulse oximeters

No in list handheld	**14**	**15**	**16**	**17**	**18**	**19**	**21**
Company	Daray	Lifebox	UTech	Aeon	Narang	SDI	Hopkins
Model	V202		UT100	A 360	DP2049	Astra	
Oximeter Cost (USD)	334	250	135	125	133	*450*	170
Sensor Cost (USD)	142	25	25	25	*NO INFO*		*NO INFO*
Extra items +costs (USD)	?	None	AC adaptor;10 Cover; 10		*NO INFO*		
Purchase Cost + 2 sensors (USD)	>618	300	195	175			
Sensor life (months)	12	12	6	6	*NO INFO*		*LOW*
Available				*NO*			
Warranty (years)	1	2	1	1	*NO INFO*		
2 year system Items +costs		P oximeter +4 sensors 350 USD	2xoximeters;270 Extras ;20 8 sensors;200 Total 490 USD	2xoximeters 250 8 sensors;200	*NO INFO*		*NO INFO*

				Total 450			
Cost/year USD	*>618*	175	245	225			
Rechargeable Battery type		Li	Ni MH cells	Li			
Battery run hours							
Battery charge hours							
AC power		yes	yes	yes			
Possible	no	yes	yes	no	no	no	no

Other pulse oximeters

There are 4 pulse oximeters in this category and the results are summarised in table 3. It is difficult to visualise how the wrist mounted devices could be used on small babies and there is a lack of information on this topic from the manufacturers of both item 22 and 23. The IRISS device (24) is not yet fully developed and may not yet be available for field trial. The other device in this category the Shanghai Berry Palm pulse oximeter has a unique sensor. However it does appear to be battery driven with no rechargeable option which is likely to be a hindrance during field testing. The manufacturer has not responded to requests for more information and therefore there is inadequate evidence available to recommend testing.

Table 3. Other pulse oximeters

No in list	**20**	**22**	**23**	**24**
Company	Shanghai Berry	Tekomed	Shanghai Berry	Guardit and Project HOPE
Model	Digital palm Pulse oximeter	Wristclinic	Wrist Pulse oximeter	IRISS
Available	yes	yes	yes	no
Oximeter Cost USD	80-100	Not known	40-50	
Sensor Cost USD	Included			
Extra items +costs USD				
Sensor Life Months	Not known			
Warranty Years	Not known			
2 year system Items +costs	Not known			
Cost/year	Not known			

USD				
Rechargeable Battery type	Charging is mentioned For 2 x AA		None	
Battery run Hours		No information On batteries		
Possible	no	no	no	yes

4. Challenges and Recommendations

4.1 Respiratory Rate Counters

There are five devices listed in Table 1 which may be worth considering further but much more information is needed to make a decision on whether or not any of them is likely to provide accurate data at an acceptable cost. The cost target should be for a maximum annual expenditure of below 100 USD which has been outlined as a possibility for pulse oximeters. Four of the five devices are in the category of “automated count” these are all dependant on the reactions of the operator who is the sensor of breaths. Only one device provides a truly automatic measurement independent of the user. This device may still not be ready for a field trial.

Further action

A specification for the cost and accuracy and availability of the respiratory rate devices should be sent to the selected manufacturers with a proposed date for final section to be made in 6 to 12 months from now. The final selection will be based on evidence to be provided by the manufacturers. There are also a few possible manufacturers who have not been listed above but who may be able to participate in this process.

Clinical considerations

It should be noted that pulse oximeters have been shown by several authors to provide data which influences mortality in children. Parallel studies do not show any correlation between respiratory rate measurements and child mortality. See ”Landscape analysis of oxygen technologies” from the University of Washington, Department of Global Health strategic Analysis 2011-09-29.

4.2 Pulse Oximeters

Handheld pulse oximeters

There are two hand held pulse oximeters which are recommended for field testing The Lifebox and the UT100 from UTech. The Aeon A360 would be worth testing but is currently not in stock. These three models are broadly similar and have estimated annual costs of USD 175 (Lifebox), 245 (UT100) and 225 (A360) based upon the manufacturer’s stated lifetimes and costs for the devices and sensors. They are all similar in construction with a measuring and display device connected to the patient by a reusable sensor. Children’s and neonatal sensors are available for each device. In summary, the Lifebox has longer life on both the device and the sensors which leads to lower annual costs .A comparative evaluation in the field should be straightforward.

Possible annual cost under 100 USD for Lifebox

During a recent informal conversation with the Lifebox administrators it was revealed that the return rate on their handheld device is about 3% per year. This indicates that a lifetime of 5 years could be obtained by purchasing 15% additional units as replacements for failed devices. In addition it is clear that the contents of the current purchasing package could be reduced by excluding unwanted items to give an initial basic cost of about 190 USD. The cost for 5 years of use would then be 190 x 1.15 =218.5 USD, an annual cost of 43.7 USD. Allowing for 2 sensors per year @25 USD each, the total annual target cost would be 93.7 USD.

Maintenance costs

The support costs for the pulse oximeters would not require any repair costs but only replacement of failed devices and sensors with new items. However I recommend that an inspection of the performance of both the handheld devices and the sensors should be carried out nationally or regionally using a specialist device at intervals of not more than six months.

5. Shortlisting

5.1 Respiratory Rate Counters

Five respiratory rate counters have been chosen for further investigation concerning their possible suitability for field testing. The available information is poor so that currently none of these devices can yet be recommended as being suitable for the expensive process of field testing in four countries. Cost and Accuracy targets should be defined before any testing is commenced.

It may be helpful to visualise the characteristics of an ideal device for fully automatic measurement respiratory rate. Clearly it should measure a parameter specific to breathing. The most specific parameters relate to air moving as a result of respiration i.e. flow, pressure, temperature, humidity, oxygen or carbon dioxide concentration. For all these measurements some sort of sensor would be required which should preferably be both disposable and cheap. This sensor should pass a signal to a hand held measuring and display device preferably with rechargeable batteries. With volume production such a device should cost <50 USD and ought to have a 5 year lifetime. The major cost of such a device as used by a Community Health Worker would be in the cost of the disposable sensor. For use on 1000 patients a year at 1USD per sensor the total cost would be 1010 USD per year per CHW. For only 100 patients the cost would be 110 USD per year. No such defined costing exists for any device in the lists. Cost targets should be set by this project. The reusable sensors in the list of existing devices do not state either their costs or the lifetime and guarantee on the sensor.

The costs for respiratory rate counters should be compared with the costing for pulse oximeters for which a potential annual cost of under USD 100 per year for any number of patients has been outlined. It needs to be established that respiratory rate measurements are potentially no more expensive than pulse oximetry if they are to be considered as being worthwhile for field testing. The category of automated count devices are probably the most likely to provide value for money.

5.2 Pulse oximeters

Two handheld pulse oximeters, the Lifebox and the UT100 from UTECH are recommended for immediate testing in the field along with the Guardit duel product and the Contec finger pulse oximeter.

5.3 Final recommendation to the Scientific Advisory Committee

Listed below are the final recommendations to the SAC for possible devices to be taken forward for Stage 2 Research. It must be noted that not all devices may be available at the time of research and would therefore have to be discounted.

Respiratory Rate Counters

1. Counting beads
2. Improved UNICEF timer
3. Philips
4. Malaria Consortium Mobile Phone Application
5. Smartcradle (Jim Black mobile phone device)
6. Nanovations (Breathe sensor)

Pulse Oximeters

1. Lifebox
2. UT100 (UTECH)
3. Contec (fingertip)

Joint RR Counter and PO devices

1. Lionsgate
2. Guardit/Inspire

Other devices which may be available and interesting to include

1. Xhale (breathe measurement)
2. University of Queensland Cough Sound Analysis

Appendix 1 – Product details of each product recommended for Stage 2 Research

Respiratory Rate Counter 1: Counting beads

Respiratory Rate Counter 2: Improved UNICEF timer

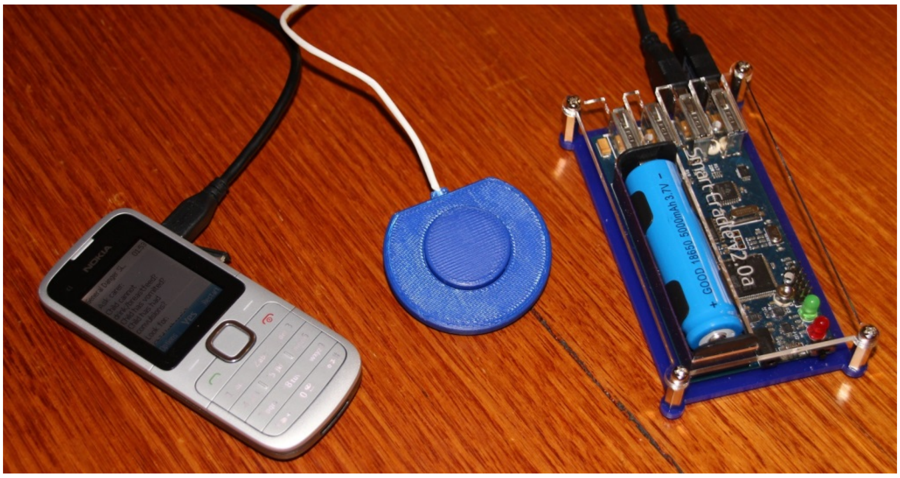
Data not available

Respiratory Rate Counter 3: Philips

Cost: Device is expected to be self-reliant with no consumables. Thus only a one-time procurement in the life cycle of the product is required with no recurring costs in between. The device will be available at an affordable price for large scale procurement.
Robustness: The device is expected to last 3-5 years at community level depending on the number of measurements per week. A rechargeable version could last 5+ years.
We are still investigating the option of having replaceable batteries, pending further requirements from UNICEF.
Scale / Applicability: The device is being iteratively designed and evaluated to address the needs of different levels of care (from community health workers to clinical officers).
Evaluations in the field with over 100 target users across different levels of care in East Africa has shown ease of use of the device and high levels of acceptability and enthusiasm.
CHW Skills: The device is designed in such a way that it can be used by illiterate/innumerate health workers. Great attention to detail is being put into the design and user experience so that it is intuitive to use and very minimum training would be required (less than half-hour) that can easily be integrated in existing CCM training programs. The device does not require technology-savviness and can be used by very low-tech users. The user interface will be very easy to use by illiterate users.
Accuracy / Scope: The health worker needs to only select the age group of the child and place the device on the child. The device will automatically detect the respiration rate and includes decision support algorithms to classify it as fast breathing rate or not. Since the guidelines include other symptoms for final diagnosis of pneumonia, the device follows the guidelines and classifies only fast breathing rate. It provides both qualitative indication and the quantitative result.
If the guidelines change, the device can be easily extended to include other vital signs measures.
Credibility: Special attention was given on how the device communicates the results to the health workers and parents. Based on the field studies in East Africa with over 100 target users, detail requirements were defined to make sure the device radiates trust and communicates results to health workers and parents in an optimal way. The device will have a professional look and feel.
Extensibility: There is no need for hard coding, unless requirements from UNICEF state otherwise.
We are currently investigating the need for different versions for different levels of care.
Availability: Depending on the requirements for testing, the device can be made available.

Respiratory Rate Counter 4: Malaria Consortium Mobile Phone Application

Respiratory Rate Counter 5: Smartcradle



Respiratory Rate Counter 6: Nanovations

Dimensions: 7cm long and 2cm width. Below the nose it is shorten to 1cm width to be compatible to children's nose.
The device is self-operated using 2 x batteries (2x3V).
The device will indicate (using RGB LEDs) whether the respiration rate is above/below/in the range therefore no intervention is needed from CHW or other staff.
The bandage will be based on medical grade bandage to support the electronic circuit.
Instructions: place the sensor below the nostril. Than use the toggle switch to turn the device ON.

Pulse Oximeter 1: Lifebox

Patient Range: Adult, Pediatrics and neonatal patients
Digital SpO2
Range 0 100%

Resolution 1%
Accuracy 70% to 100%: ±2%
Refreshing rate < 13 seconds
Pitch Tone Yes
Pulse Rate
Resolution 1 bpm
Accuracy ±2% or ±1 bpm, whichever is the greater
Refreshing rate < 13 seconds
Display
Type 2.4" color display 320 x 240 pixels
Parameter
Digital SpO2, Pulse Rate, Pleth bar & SpO2 waveform
Alarm
Audible alarm, audible button tone
Supports Pitch Tone and multilevel volume
Alarm tones meet the requirement of IEC 6060118
Appearance
Dimension 123mm (H) x 58.5mm (W) x 28mm (D)
Weight < 200g
Data Storage
Display Trend table
Trend interval 2 seconds to 30 minutes
Trend parameter PR, SpO2
Trend data spotcheck mode: ID from 1 to 99, 300 records for each ID
Battery
Type 3 AA Alkaline batteries or NIMH rechargeable battery (optional) or Lithium ion rechargeable battery (option)
Runtime 14 hours standard use
Nellcor SpO2 probecompatible
Safety Standards
CE classification: IIb
Type of protection against electric shock: II, with internal power device
Degree of protection against electric shock: CF
Degree of protection against ingress of liquid: IPX1

Pulse Oximeter 2: UT100 (UTECH)

Parameters: SpO2, pulse rate, ETCO2, and RR
Power supply
• AC power: 100-240VAC,47-63Hz
• Four AA 1.5V alkaline or Ni-MH cells
SpO2
• Range:0-100%
• Accuracy:±2 at 70-100%
• Resolution: 1%

• Display Response: The display is for functional saturation. The pulse strength bar graph is not proportional to pulse volume.
Pulse rate
• Range: 30-250bpm
• Accuracy: ±2 at 30-250bpm
• Resolution: 1bpm
ETCO2
• Range: 0% ~ 20% (0 ~ 150mmHg)
• Accuracy: ±2 mmHg @ 5.0% CO_2 (at BTPS), < 10% of reading @ > 5.0% CO_2 (at BTPS)
• Resolution: 0.1 mmHg
• Display Response: The display is for functional saturation. The pulse strength bar graph is not proportional to pulse volume.
RR
• Range: 0~150 (BPM)
• Accuracy: ±1bpm
• Resolution: 1bpm

Pulse Oximeter 3: Contec

Main Performance: SpO2 value display, Pulse rate value display
• Bar graph display
• Pulse waveform display
• Pulse sound indication
Main Parameters
<u>Measurement of SpO2</u>
Measuring range: 0% ~ 100%
Accuracy: 70% ~ 100% ±Below 70%: unspecified
<u>Measurement of pulse rate</u>
Measuring range: 30bpm ~250bpm
Accuracy: ±2bpm or ±2%
Resolution
SpO2: 1%, Pulse rate: 1 bpm
Power supply requirement
3.6V DC~4.2v DC

Joint RR Counter and PO device 1: Lionsgate

Joint RR Counter and PO device 2: Guardit/Inspire

1.5 x 1.5 Inch Display
Re-useable Electrode Hands
Wireless Interface
Rechargeable Battery
Water Resistant
Sensor Array: Temperature, Anxiety, Position, Heart Rate, Respiratory Rate, Inspire Algorithm
Inspire Algorithm: Cellular Integration, Application for Protocol Design, Field and Clinical Manuals, Hand Charging Unit

Other device 1: Xhale (breathe measurement)

Data not available

Other device 2: University of Queensland Cough Sound Analysis

Data not available